



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)
Canada Hazardous Products Regulations (SOR/2015-17)

Revision date 30-May-2025

Revision Number 6

1. Identification

Product identifier

Product Name CAB-O-SIL® M-5P Untreated Fumed Silica - Pharmaceutical Grade

Other means of identification

Product Code(s) M5P

Synonyms Untreated Fumed Silica, Silicon Dioxide, Synthetic Amorphous Silica, Pyrogenic (Fumed) Amorphous Silica, Colloidal Silicon Dioxide, Colloidal Anhydrous Silica, Light Anhydrous Silicic Acid

Recommended use of the chemical and restrictions on use

Recommended use Multifunctional excipient for pharmaceutical solid, semi-solid, and liquid forms, Free flow agent, Anti-caking agent, Spray aid, Anti-blocking agent, Anti-settling agent, Thickening agent, Stabilization agent, Carrier, Other

Restrictions on use None known

Details of the supplier of the safety data sheet

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2. Hazard(s) identification

Classification

This product is not considered hazardous by either the US 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200) or the Canadian Workplace Hazardous Material Information System (WHMIS 2015)

Label elements

Signal word
None

Hazard statements
None

Precautionary statements

None

Other information

May cause mechanical irritation. Dust may be irritating to respiratory tract.

3. Composition/information on ingredients

Substance

Synonyms Untreated Fumed Silica, Silicon Dioxide, Synthetic Amorphous Silica, Pyrogenic (Fumed) Amorphous Silica, Colloidal Silicon Dioxide, Colloidal Anhydrous Silica, Light Anhydrous Silicic Acid

Chemical name	CAS No.	Weight-%
Amorphous Silicon Dioxide, chemically prepared	7631-86-9	100

4. First-aid measures

Description of first aid measures

Inhalation	If cough, shortness of breath or other breathing problems occur, move to fresh air. Seek medical attention if symptoms persist. If necessary, restore normal breathing through standard first aid measures.
Eye contact	In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if symptoms occur.
Skin contact	Wash skin with soap and water. Get medical attention if symptoms occur.
Ingestion	Do NOT induce vomiting. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Symptoms See Section 11 for additional Toxicological Information.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media	Silica is non-combustible, therefore no extinguishing media needs to be identified.
Unsuitable extinguishing media	None.
Specific hazards arising from the chemical	None.
Hazardous combustion products	None
Explosion data	
Sensitivity to mechanical impact	None.
Sensitivity to static discharge	This material is an inorganic dust and will not create nor support conditions that would result in a dust explosion or fire. Take precautionary measures against static discharges. Avoid generation of dust. All metal parts of the mixing and processing equipment must be earthed/grounded. Ensure all equipment is electrically earthed/grounded before beginning transfer operations.

Special protective equipment and precautions for fire-fighters

In case of fire: Wear self-contained breathing apparatus. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions

Avoid generation of dust. Ensure adequate ventilation. Use personal protective equipment as required. See section 8.

Environmental precautions

Environmental precautions

Local authorities should be advised if significant spillages cannot be contained. See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment

Contain spilled product on land, if possible. Prevent further leakage or spillage if safe to do so.

Methods for cleaning up

Clean up promptly by vacuum. Use of a vacuum with high efficiency particulate air (HEPA) filtration is recommended. Do not create a dust cloud by using a brush or compressed air. Pick up and transfer to properly labeled containers. See section 13.

7. Handling and storage

Precautions for safe handling

Advice on safe handling

Avoid contact with skin and eyes. Avoid generation of dust. Do not breathe dust. Provide appropriate local exhaust ventilation at machinery and at places where dust can be generated. Do not create a dust cloud by using a brush or compressed air.

Take precautionary measures against static discharges. All metal parts of the mixing and processing equipment must be earthed/grounded. Ensure all equipment is electrically earthed/grounded before beginning transfer operations. Fine dust is capable of penetrating electrical equipment and may cause electrical shorts.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions

Keep container tightly closed in a dry and well-ventilated place. Do not store together with volatile chemicals as they may be adsorbed onto product. Store at ambient conditions. Keep in properly labeled containers.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

The table below is a summary. Please see the specific legislation for complete information.

Chemical name	Amorphous Silicon Dioxide, chemically prepared 7631-86-9
OSHA PEL	(vacated) TWA: 6 mg/m
Chemical name	Dust, or particulates not otherwise specified RR-00072-6
ACGIH TLV	TWA: 10 mg/m ³ inhalable particles, recommended TWA: 3 mg/m ³ respirable particles, recommended

OSHA PEL	TWA: 15 mg/m ³ total dust; 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust; 5 mg/m ³ respirable fraction
Alberta	TWA: 10 mg/m ³ total; 3 mg/m ³ respirable
British Columbia	TWA: 10 mg/m ³ total dust; 3 mg/m ³ respirable fraction
Ontario	TWA: 10 mg/m ³ inhalable fraction; 3 mg/m ³ respirable fraction
Quebec	TWA: 10 mg/m ³ total dust

Appropriate engineering controls

Engineering controls Ensure adequate ventilation to maintain exposures below occupational limits. Provide appropriate local exhaust ventilation at machinery and at places where dust can be generated. Ensure that eyewash stations and safety showers are close to the workstation location.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles). Appropriate eye/face protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.

Hand protection Wear protective gloves to prevent soiling of hands. Use protective barrier cream before handling the product. Appropriate hand protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.

Skin and body protection Wear suitable protective clothing. Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed out of the workplace. Appropriate skin and body protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.

Respiratory protection Approved respirator may be necessary if local exhaust ventilation is not adequate. Appropriate respiratory protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.

Environmental exposure controls In accordance with all local legislation and permit requirements as applicable for dusts.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid
Appearance Powder
Color white
Odor None
Odor threshold Not applicable

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	3.6 - 4.5	In-house testing
Melting point / freezing point	1700 °C	NIOSH Pocket Guide to Chemical Hazards
Boiling point / boiling range	2230 °C	NIOSH Pocket Guide to Chemical Hazards
Flash point		Not combustible
Evaporation rate		Not applicable
Flammability (solid, gas)		Not flammable. Product resists ignition and does not promote flame spread
Flammability Limit in Air		Not applicable
Vapor pressure		Not applicable
Relative vapor density		Not applicable
Relative density	2.2	@ 20 °C

Water solubility	Soluble	According to OECD 105, enhanced
Solubility(ies)		No data available
Partition coefficient		Not applicable
Autoignition temperature		Not applicable
Decomposition temperature		Not applicable
Kinematic viscosity		Not applicable
Dynamic viscosity		Not applicable
<u>Other information</u>		
Minimum Explosive Conc.		Not applicable
Minimum Ignition Temperature		Not applicable
Minimum Ignition Temperature - Layer		Not applicable
Minimum Ignition Energy		Not applicable
Maximum Pressure Rise		Not applicable
K _{st}		Not applicable
Explosive properties		Non-explosible
Oxidizing properties		No Oxidizing properties
Bulk density	30-150 kg/m ³	DIN/ISO 787:11
VOC Content (%)		Not applicable

10. Stability and reactivity

Reactivity	Not reactive. Substance is an inert inorganic solid.
Chemical stability	Stable under normal conditions. Stable under recommended storage conditions.
Possibility of hazardous reactions	None under normal processing.
Hazardous polymerization	Hazardous polymerization does not occur.
Conditions to avoid	None known.
Incompatible materials	None known
Hazardous decomposition products	None known

11. Toxicological information

Acute toxicity

Oral LD50	> 5000 mg/kg (rat). No deaths occurred and no signs of toxicity were seen during the observation periods after single oral administration of silica(OECD 401).
Dermal LD50	> 2000 mg/kg (rabbit). Very slight transient erythema in one animal. No signs of systemic or organ toxicity (OECD 402).
Inhalation LC50	Due to the product's physical characteristics, no suitable testing procedure is available.
Skin corrosion/irritation	Primary irritation index = 0/8 @ 24 hr. Not classified as an irritant (OECD 404).
Serious eye damage/eye irritation	Draize score 1.0/110 @ 24 hr. Not classified as an irritant in rabbit studies (OECD 405). High dust concentrations may cause mechanical irritation.
Respiratory or skin sensitization	No experimental animal data are available. No cases of sensitization in humans have been reported.
Germ cell mutagenicity	Not mutagenic in AMES Test. Negative in the unscheduled DNA synthesis assay. Negative in the

	chromosome aberration test in Chinese hamster ovary (CHO) cells.
Carcinogenicity	No evidence of carcinogenicity was observed in multiple animal species following repeated oral or inhalation exposure to amorphous silica. Similarly, epidemiology studies show no evidence of carcinogenicity in workers who manufacture amorphous silica.
Reproductive toxicity	No effects on reproductive organs or fetal development have been reported in animal toxicity studies.
STOT - single exposure	Based on available data, specific target organ toxicity is not expected after single oral, single inhalation, or single dermal exposure.
STOT - repeated exposure	Repeated dose toxicity: oral (rat), 2 weeks to 6 months, no significant treatment-related adverse effects at doses of up to 8% silica in the diet. Repeated dose toxicity: inhalation (rat), 13 weeks, Lowest Observed Effect Level (LOEL) = 1.3 mg/m ³ based on mild reversible effects in the lungs. Repeated dose toxicity: inhalation (rat), 90 days, LOEL = 1 mg/m ³ based on reversible effects in the lungs and effects in the nasal cavity. Repeated dose toxicity using SAS 400 m ² /g: inhalation (rat), 90 days, fully reversible inflammation related to clearance processes following recovery period. NOAEC (lung) based on histopathology and inflammatory marker is 5 mg/m ³ Based on available data, a STOT-RE classification is not warranted.
Target organ effects	Lungs
Aspiration hazard	Based on industrial experience and available data, no aspiration hazard is expected.
Other adverse effects	No information available.

12. Ecological information

Ecotoxicity	Fish (Brachydanio rerio) LC50 (96 h): > 10,000 mg/l; (Method: OECD 203). No acute toxicity to Daphnia with EL and EL ₅₀ ranging from >1000 to 10,000 mg/L (OECD 202).
Persistence and degradability	The methods for determining biodegradability are not applicable to inorganic substances.
Bioaccumulation	Not expected due to physicochemical properties of the substance.
Mobility	Not expected to migrate.
Other adverse effects	No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with federal, state and local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable.
US EPA Waste Number	Unused product is not a hazardous waste under U.S. RCRA, 40 CFR 261

14. Transport information

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>ICAO (air)</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated
<u>RID</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	Not regulated

15. Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

TSCA	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	Complies
IECSC	Complies
KECI	Complies
PICCS	Complies
AIIC	Complies
TCSI	Complies
NZIoC	Complies

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AIIC - Australian Inventory of Industrial Chemicals

TCSI - Taiwan Chemical Substance Inventory

NZIoC - New Zealand Inventory of Chemicals

US Federal Regulations

TSCA Section 12(b) Export Regulations

This product does not contain any components that are subject to TSCA 12(b) Export Notification.

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

Clean Air Act Amendments of 1990 (CAA, Section 112, 40 CFR 82)

This product does not contain any components listed as a Hazardous Air Pollutant, Flammable Substance, Toxic Substance, or Class 1 or 2 Ozone Depletor.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations.

Chemical name	New Jersey	Massachusetts	Pennsylvania
Amorphous Silicon Dioxide, chemically prepared 7631-86-9	X	X	X

16. Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Key literature references and sources for data used to compile the SDS

NIOSH Pocket Guide to Chemical Hazards, September 2005. "Silica, amorphous". DHHS (NIOSH) Publication No. 2005-149. National Technical Information Service, Springfield, VA. p. 277

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End of Safety Data Sheet